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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,751	01/30/2002	Jack D. Mc Neal	2021-045	7055
7590	11/20/2003			EXAMINER COURSON, TANIA C
Jeffrey G Sheldon Sheldon & Mark 225 South Lake Avenue 9th Floor Pasadena, CA 91101			ART UNIT 2859	PAPER NUMBER
DATE MAILED: 11/20/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/060,751	MC NEAL ET AL.
	Examiner Tania C. Courson	Art Unit 2859

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 September 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-24 and 27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-24 and 27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 15 September 2003 is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) All    b) Some \*    c) None of:
 

- 1. Certified copies of the priority documents have been received.
- 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

    a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u>	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4-8, 10-13, 17-18, 22-24 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Cadell et al. (US 6,195,158 B1).

Cadell et al. disclose in Figures 1-4, an apparatus and method for a blood analyzer comprising:

With respect to apparatus claims 22 and method claims 1, 12, 18, 23 and 27 comprising the steps of:

- a) projecting onto the container a first detecting light beam/source of visible light (Fig. 1, LEDs 16) that is substantially transmitted by serum, plasma and a material but substantially blocked by cells, a portion of the first detecting light beam being transmitted through the container (column 3, line 66 through column 4, line 14);
- b) projecting onto the container a second detecting light beam/source of infrared light (Fig. 1, LEDs 16) that is substantially blocked by serum, plasma, and cells, but is substantially transmitted by the material, a portion of the second detecting

light beam being transmitted through the container (column 3, line 66 through column 4, line 14);

- c) detecting, with a first detector (Fig. 1, detectors 20), as a function of position along the vertical axis of the container, the portion of the first detecting light beam that is transmitted through the container and no significant portion of the second detecting light beam (column 3, line 66 through column 4, line 14);
- d) detecting, with a second detector (Fig. 1, detectors 20), as a function along the vertical axis of the container, the portion of the second detecting light beam that is transmitted through the container and no significant portion of the first detecting light beam (column 3, line 66 through column 4, line 14), and;
- e) determining, with a processor, the location of at least one interface from the detected portions (column 3, line 66 through column 4, line 14);

With respect to claim 4:

- a) wherein the container is a test tube (Fig. 1, tube 22);

With respect to claim 5:

- a) wherein the container contains an upper layer of plasma or serum, and a lower layer of cells (Fig. 1);

With respect to claim 6:

- a) wherein a plurality of labels are on the container (column 2, lines 2-4 and lines 46-48);

With respect to claim 7:

- a) wherein the first and second detecting light beams are projected by a projector and detected by detector and wherein the projector and detector are substantially aligned so that the light beams strike the container substantially perpendicular to the axis of the container (Fig. 1);

With respect to claims 8 and 13:

- a) wherein the container further contains a middle layer of gel between the layer of serum or plasma and the layer of cells, and both light beams are substantially transmitted by the gel (Fig. 1, gel 26);

With respect to claim 10:

- a) wherein the light beams are projected by a laser (Fig. 3, laser 28);

With respect to claim 11:

- a) wherein the light beams are projected by fiber optic (Fig. 2, fiber optic 10);

With respect to claim 17:

- a) wherein the container has at least one label on its exterior that obscures at least one interface (column 2, lines 2-4 and lines 46-48);

With respect to claim 24:

- a) wherein the location of the interface that is determined is the location between air and the contents of the container (Fig. 1);

3. Claims 1, 9 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Kawano (US 2002/0067476 A1).

Kawano discloses in Figure 1, an analytical method for blood comprising:

With respect to method claim 1 comprising the steps of:

- a) projecting onto the container a first detecting light beam (Fig. 1, optical fiber 7) that is substantially transmitted by serum, plasma and a material but substantially blocked by cells, a portion of the first detecting light beam being transmitted through the container (paragraph 33, line 6 through paragraph 34, line 5);
- b) projecting onto the container a second detecting light beam (Fig. 1, optical fiber 7) that is substantially blocked by serum, plasma, and cells, but is substantially transmitted by the material, a portion of the second detecting light beam being transmitted through the container (paragraph 33, line 6 through paragraph 34, line 5);
- c) detecting (Fig. 1, optical sensor within apparatus 1), as a function of position along the vertical axis of the container, the portion of the first detecting light

beam that is transmitted through the container and no significant portion of the second detecting light beam (paragraph 30, lines 4-9);

- d) detecting (Fig. 1, optical sensor within apparatus 1), as a function along the vertical axis of the container, the portion of the second detecting light beam that is transmitted through the container and no significant portion of the first detecting light beam (paragraph 30, lines 4-9), and;
- e) determining the location of at least one interface from the detected portions (Fig. 1, computer 2 and paragraph 36, line 1-5);

With respect to claim 9:

- a) wherein a cap is covering the container (Fig. 1, cap 6).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-3, 14-16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cadell et al.

Cadell et al. disclose an apparatus and method for a blood analyzer, as stated above in paragraph 7.

Cadell et al. do not disclose wherein a material is plastic, a material is glass, wherein the wavelength of the first light beam is from about 300 nm to about 1200nm, wherein the wavelength of the second light beam is from about 1.4  $\mu$ m to about 2.8  $\mu$ m, wherein the wavelength of the second light beam is from about 3.8  $\mu$ m to about 6.8  $\mu$ m

Regarding claims 2-3: Cadell et al. disclose the test tube (tube 22) made of a material. The particular type of material used to make the test tube, absent any criticality, is only considered to be the use of a "preferred" or "optimum" material out of a plurality of well known materials that a person having ordinary skill in the art at the time the invention was made would have find obvious to provide using routine experimentation based, among other things, on the intended use of Applicant's apparatus, i.e., suitability for the intended use of Applicant's apparatus. See In re Leshin, 125 USPQ 416 (CCPA 1960) where the court stated that a selection of a material on the basis of suitability for intended use of an apparatus would be entirely obvious.

Regarding the wavelength of the first light beam and the second light beam: Cadell et al. discloses different wavelengths (column 3, lines 23-35) but does not disclose a particular value for this parameter. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a wavelength of the first light beam from about 300 nm to about 1200nm, a wavelength of the second light beam from about 1.4  $\mu$ m to about 2.8  $\mu$ m, the wavelength of the second light beam from about 3.8  $\mu$ m to about 6.8  $\mu$ m, since it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the “optimum range” involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Response to Arguments***

6. Applicant's arguments filed on September 15, 2003, have been fully considered but they are not persuasive.

7. Applicant's comment regarding the lack of suggestion in Kawano, for “projecting two different light beams” is not persuasive because it is noted that Kawano does indeed show “two different light beams”, via the various wavelength ranges. Each wavelength is considered a different light beam, thus “two light beams” as is shown in Fig. 1. The applicant is not claiming that the “light beams” are projected simultaneously onto to a specific point of the container.

8. Applicant's comment regarding the lack of suggestion in Cadell et al. for “projecting multiple light beams” is not persuasive because it is noted that Cadell et al. does indeed show “multiple light beams”, via the multiple LEDs. Each LED is considered a light beam, thus “projecting multiple light beams” as is shown in Fig. 1. The applicant is not claiming that the “light beams” are projected simultaneously onto to a specific point of the container.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tania C. Courson whose telephone number is (703) 305-3031. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez, can be reached on (703) 308-3875. The fax number for this Organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



DIEGO F.F. GUTIERREZ  
SUPERVISORY PATENT EXAMINER  
GROUP ART UNIT 2859

TCC  
November 17, 2003